

Remarks/Arguments

Claims 1-4, 7-9, 14, 15, 18, 21, 24, and 27-30 were examined in the outstanding final office action mailed on 10/28/2008 (hereafter "Outstanding Office Action"). All claims were rejected. By virtue of this paper, claims 1, 2, 3, 7, , 14, 15, 18, 21, 24, 27, and 28 are sought to be amended, claims 4-6, 9-13, 16-17, 19,20, 22,23 , 25,26, 29 and 30 are sought to be canceled, and new claims 31-32 are sought to be added. The amendments and additions are believed not to introduce new matter, and their entry is respectfully requested. The cancellations and amendments are made without prejudice or disclaimer. Claims 1, 2, 3, 7,8, 14,15, 18, 21, 24 , 27,28, 31 and 32 are respectfully presented for consideration further in view of the below remarks.

Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) and in compliance with 37 CFR 1.125 (b) and (c) is submitted herewith. A marked version showing deleted material as crossed out lines and added material as underlining and also a clean version of substitute specification is submitted herewith. The substitute specification contains no new matter. Applicant respectfully requests Examiner to enter substitute specification.

Claim Rejections - 35 U.S.C. § 101

Applicant thanks Examiner for suggestions to avoid rejections of claims under 35 U.S.C. § 101. Terms "engagable" and "capable of" are used in amended claims as per examiner's suggestion to avoid rejection under 35 U.S.C. § 101.

Claim Rejections - 35 U.S.C. § 112

On page 3 of Final Office Action mailed on October, 28, 2008 , the Examiner rejected Claims **1-3,7-9,14-15,18,21,24,27** under 35 U.S.C.§ 112 , second paragraph . The Examiner is thanked for continuing examination, and thereby furthering prosecution. Applicant has amended said claims so that there is proper antecedent basis and to further defines Applicant's invention. No new matter has been introduced and the amended claims, which are believed to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

On page 3 of the Outstanding Office Action **Claim 28** was rejected under **35 U.S.C. § 102(b)** as being anticipated by Bosacco US 3,670,724. Applicant respectfully requests entry of amended independent Claim 28. Claim 28 has been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g. paragraphs [[0024],[00036],[00048],[00086],[00087],[00089],[00092],[00093],[00096], Figs. 3,9,15,21,24,25,28,30 and 31. Applicant submits that "Bosacco" (US 3,670,724) does not suggest or teach or disclose each and every feature or element of amended claim 28. For example Bosacco does not teach or suggest plane of center of first plurality of proximal holes located in head part of intramedullary nail extending to midsection of head and neck portion of femur bone and plane of center of a first plurality of distal holes located in intermediate portion of intramedullary nail extending to midsection of shaft of femur bone and both are intersecting with each other. Instead, as Bosacco teaches "intramedullary nail 17 as illustrated in Fig 9 is employed having a plurality spaced apertures 17a throughout most of its length " (Col. 2 ll 57-60) . Bosacco does not disclose plane of apertures 17 a extending through midsection of head and neck portion of femur or it discloses orientation of aperture 17a of intramedullary nail 17 as shown in Fig 7. - Bosacco (US 3,670,724.) of allowing engagement of sliding smooth part of proximal hip pins slidably in aperture 17a or aperture 22a of plate 22 and triflanged part engagable to head and neck portion of femur bone 19 (Emphasis added). Applicant also points out that because intramedullary nail 17 disclosed by Bosacco is not connectable with targeting device and method of its insertion is disclosed that "The nail 17 is driven in retrograde fashion through the medulla 19c of bone 19 and the fracture is reduced "(Col. 2 ll 61-63); because of this Bosacco teaches away from having insertion of intramedullary nail by invasive way by opening the fracture site. Bosacco does not disclose element of a plurality of barrels along with intramedullary nail and buttress plate which is essential in situations when lateral cortex of femur bone is broken very badly and there is fracture gap even after fixation and drilled hole in lateral cortex is not uniform due to broken lateral cortex there is no smooth uniform sliding surface for sliding of smooth sliding part of proximal hip pins and there is no lateral support or platform for controlled sliding of proximal hip pins to allow controlled collapse of fracture gap for

bone to bone contact , where barrels along with buttress plate are essential to provide support and platform to broken lateral cortex and barrels provide uniform gliding surface . Applicant further points that Bosacco disclose a rigid member –intramedullary nail (Emphasis added) having a first set of spaced apertures and a rigid plate having a second set of apertures spaced from one another identically to the spacing of apertures in said first set (Col. 4 Claim 1 a. and b. ll.1-8), while applicants discloses first plurality of proximal holes of intramedullary nail and central large holes of buttress plate ; first plurality of distal holes of intramedullary nail and small holes in buttress plate are not identically placed though they match with each other in angular fashion and they are not placed throughout most of length of intramedullary nail or plate. Applicant further points that Bossaco discloses requirement of making burr hole 19b drilled in lateral femoral shaft large enough so that at least one of the holes 17 a would be visible through hole 19b (Col 2 ll 66-72) , thus Bosacco teaches to make hole 19b in femur bone large enough to see by naked eye (emphasis added) hole 17a to provide fixed reference point which may not be exactly positioned for reference as not made with any reference targeting device and making such large hole will weaken further lateral cortex of femur bone and which is already weakened by fracture, which is contrary to teaching by applicant's disclosure. Bosacco teaches away by disclosing intramedullary nail 17 having plurality of spaced apertures 17a throughout most of its length (Col 2 ll; 57-60), this feature creates stress risers at multiple points and weakening the intramedullary nail and assembly which is likely not to withstand higher forces at proximal femur fractures. Applicant further points that Bossaco recites the method of treating human bone which requires exposure of bone on either side of fracture area and also fracture area to position rigid bone plate and to align identical second set of apertures in plate and first set of apertures in intramedullary rigid member and drill large enough hole in bone to make visible one of the first set. apertures of rigid member placed in medulla of bone , further recites that plate is removed before fasteners are inserted (Col 4 ll 23-45),thus it appears that Bosacco intends to use plate member temporarily as internal guide only. Applicant further points that Bossaco discloses use of intramedullary nail placed inside medulla of bone and plate placed on exterior of bone, when finally fixed with fasteners through each other, it does not allow collapse of fracture gap and bone to bone contact later on weight bearing by patient , thus Bosacco teaches static fixation, which is contrarily to

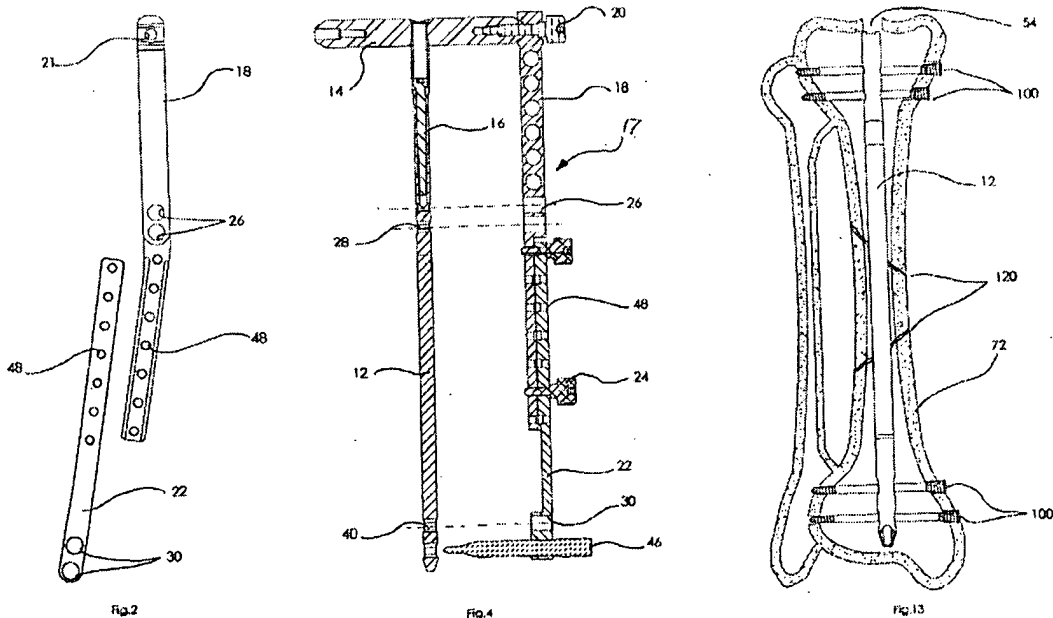
teaching by Applicant's disclosure. Applicant further points out that Bosacco teaches use of plate fixed on exterior surface of bone rigidly not to allow any movement between screw and nail and plate and also due to rigidity and compression hampers blood supply to external layer of bone that is periosteum which is very vital for new bone formation and healing of fracture, thus teaches away from applicants disclosure where plate is cooperating with intramedullary nail in buttress mode without hampering blood supply to the periosteum and allows backward movement of proximal hip pin within nail holes and barrels and central large holes of plate allowing collapse of fracture gap. Accordingly, Bosacco does not teach or describe, expressly or inherently, each and every element as set forth in amended claim 28 nor does Bosacco have elements arranged as required by this amended claim 28. As such, Bosacco does not anticipate or render obvious independent claim 28. Applicant respectfully requests entry and allowance of Claim 28.

Claim Rejections Under 35 U.S.C. § 103

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Zirkle, US 2002/0151897** in view of **Behrens US 6,932,818**. Applicant respectfully requests entry of amended independent Claim 1. Claim 1 has been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g. paragraphs [[0005],[0016],[00028],[00040],[00086],[00087],[00096], **Figs. , 9, 28 and 31**. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the according to amended claim 1 and other claims, present invention is constructed structurally different from device of Zirkle and device of Behrens and is used in an entirely different manner, thereby overcoming drawbacks in the apparatus of Zirkle and apparatus and method of Behrens, as well as many similar devices known in the prior art of record.

Apparatus described by Zirkle is to secure intramedullary nail in long bone fractures with jig to locate transverse apertures in intramedullary nail and particular object of invention is to locate "lower" (distal) holes in cases and places where sophisticated equipment like real time x-ray imaging is not available for locating or where the economics of the practice do not permit such equipment (**Page 1 Para [0003], [0004], [0005], [0013]**). Zirkle discloses an elongate orthopedic **IM nail 12** secured to **T handle 14** and a **jig 17** comprising a **proximal target arm 18** removably affixed to T handle with **shoulder cap**

screw 24 through aperture 21 in proximal target arm 18 and into an aperture 56 in the end of T handle 14, while distal target arm 22 is affixed to the proximal target arm 18 by one or more cap screws 24. The proximal target arm 18 is provided with one or more proximal apertures 26 aligned with proximal apertures 28 in IM nail 12. The distal target arm 22 is likewise provided with one or more distal apertures 30 aligned with distal apertures 40 in the IM nail. (Page 2 Para [0032]). Zirkle further discloses that apertures 28 and 40 are disposed along a longitudinal axis of the IM nail such that a portion of apertures are located above the point of fracture and a portion of aperture are located below the point of fracture. As Examiner has stated in Final Office Action, Fig 2 (shown below) in Zirkle's Application, first plurality of proximal holes/distal holes correspond to second plurality of proximal/distal holes and where the second plurality of proximal holes and the second plurality of distal holes are in different plane. If Figures 2, Figure 4 and Figure 13(as shown below) are seen in details , it shows that plane of first plurality of proximal holes and plane of first plurality of distal holes are in different plane but they are parallel and don't intersect with each other.



Thus Zirkle does not teach to have structure of a first plurality of proximal holes 28 and structure of a first plurality of distal holes 40 disposed in IM Nail 12, where, a plane of

centre of a first plurality of proximal holes 28 in IM nail 12 are extendable to midsection of head and neck portion of femur bone and a plane of centre of a first plurality of proximal holes is intersecting with a plane of first plurality of distal holes. Zirkle describes apparatus mainly to solve the problem of targeting distal blind holes in IM nail without the help of real-time expensive imaging equipment. Zirkle describes that there is no difficulty in targeting the proximal holes and problem of targeting the distal holes due to its distance from connection between targeting jig with IM nail and more chances of deflection of nail due to natural curvature of shaft of bone (Paragraph [0035]). Zirkle provides apparatus like slot finder (Para [0037]) after drilling large diameter hole in near cortex to feel (in absence of real time imaging equipment) the aperture in nail and also further describes in certain situation where there is still difficulty in locating the distal hole by slot finder, he suggests [Para 0038] to even remove Jig 17 to have more freedom to surgeon to search the aperture 40 by rotating the slot finder. This may be due to long cantilever lever arm of distal targeting arm from connection of jig to IM nail, too many joining parts e.g. T handle with Nail, T handle with proximal targeting arm and proximal targeting arm with distal targeting arm and no other support to long targeting arm except connection at T handle and also due to difference in curvature of nail and bone and deflection of nail within medulla of bone. Due to long, cantilver arrangement of targeting arm, it allows lateral movement of distal targeting arm away from desired parallel alignment with nail, causing misalignment of the distal holes with corresponding holes in IM nail requiring larger diameter drilling in near cortex leading to larger incision and invasiveness, which is contrarily to applicant's disclosure

Behrens has suggested solution to this problem by providing at least one anchoring pin secured to socket within an intramedullary nail, at a location near a fractured end of long bone and spaced from the end of bone to place the anchoring pin at the shaft of the bone in that socket, a drill guide then coupled to and fully supported by anchoring pin, placing a drill guide passage in close proximity to the fracture reducing lever arm for accurate and reliable alignment and with drilling exactly with minimal invasiveness(Col.2 ll 30-60). Behrens describes apparatus providing drill guide block attached firmly with anchoring pin affixed threadably with socket within intramedullary nail, where drill guide comprising drill passages in direction of head and neck of femur and drill passages in direction of shaft of femur, both are in parallel plane (Figs 5 and 9 shown below).

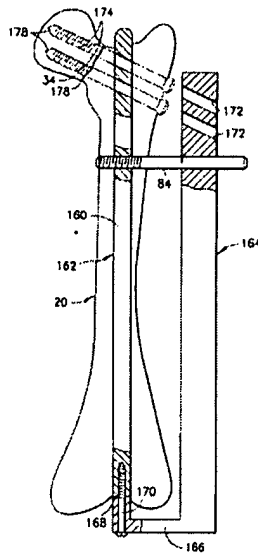


FIG. 5

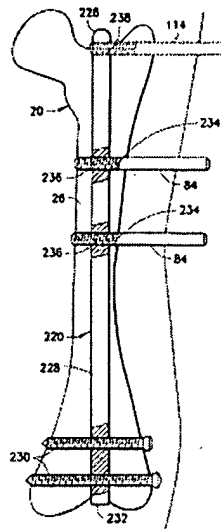


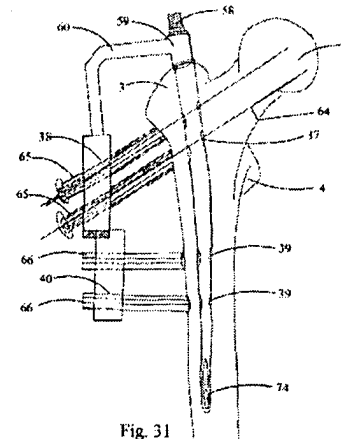
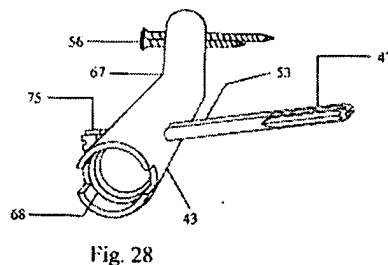
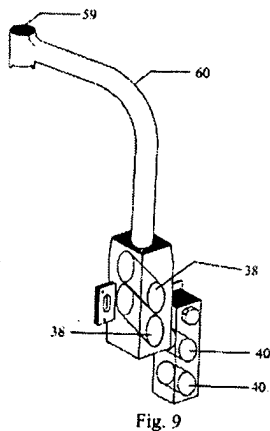
FIG. 9

Generally, with normal anatomy of femur bone, midsection of head –neck portion of femur bone is placed in plane intersecting the plane of midsection of shaft of femur bone. In case of fracture of proximal femur located near junction between head –neck portion and shaft of femur bone this anatomical relationship is disturbed and transmission of body forces becomes uneven and inefficiently, leading to healing in misalignment with pain and limp or loss of fixation and cut through of head and neck portion by proximal hip pin leading to pain ,limp and disability. In case of fractures of proximal femur located near junction between head –neck portion and shaft of femur bone , fixation of fasteners to midsection of head and neck slidably through proximal apertures in intramedullary nail targeted by corresponding apertures in targeting device in first plane and fixation of locking screws to midsection of shaft of femur bone through distal apertures in intramedullary nail targeted by corresponding apertures in targeting device in second plane which is intersecting with first plane is required by surgeon to maintain anatomical reduction of fracture and to transmit and distribute forces equally to prevent misalignment and to facilitate controlled collapse of fracture gap. Apparatus described by Zirkle or similar apparatus with modification like Behrens or others providing intramedullary nail with apertures directed at angle and jig with corresponding drill guide passages targeting head and neck portion of the femur bone are known in prior art , but they are not able to solve the problem of fixation of screws or fasteners in midsection

of head and neck portion of femur in first plane and fixation of nail with locking screws engaging midsection of shaft of femur bone in second plane intersecting with first plane, both simultaneously without rotating jig or targeting device and intramedullary nail mounted on it. With the use of apparatus described by Zirkle or similar apparatus with modification like Behrens or others having plane and structure of proximal holes and distal holes parallel, surgeon has three undesired possibilities, first possibility is to have reduction of fracture and alignment of head and neck fragment with shaft in one plane that is non anatomical and fix the fracture in that position which is not desirable, second possibility is to have desired anatomical reduction and have engagement of proximal hip pins in midsection of head and neck of femur in desired position by rotating jig and nail mounted thereof leading to alignment of distal holes in jig and nail in odd position to fix with fear of damaging vital structure like vessel or nerve while drilling and abandoning the distal locking screw leading to rotationally insecure fixation of assembly and possible undesired outcome of loss of fixation and third possibility is to have desired anatomical reduction and have engagement of distal locking screws in midsection of shaft of femur bone and have engagement of proximal hip pins in head and neck eccentrically leading to very high possibility of failure of fixation by cut through of hip pins from head and neck- commonest complication and undesired event. So none of the assembly of Zirkle or Behrens or similar described in prior art provides fixation of proximal hip pins (through proximal holes in nail) in midsection of head and neck portion of femur bone and simultaneously allow fixation of distal locking screws (through distal holes in nail) in midsection of shaft of femur bone leading to desirable outcome. Applicant points further that Behrens describes (Col 3 ll 30-Col 4 ll 45) the use of retrograde nail 220 inserted from inter condylar notch 30 and up to pyramidal fossa 208, the retrograde nail 220 is locked in place utilizing two locking screws 230 placed adjacent the second end 232 of the nail shank 228 and passing through nail shank 228, then two holes 234 are drilled in the femoral shaft 26 in alignment with socket 236 in nail shank 228, anchoring pins 84 are secured with socket by threaded connection at 86 with outward extension 88, once the anchoring pins are place, a drill guide 90 is coupled to anchoring pins 84, drill guide 90 includes drill guide passages 94, thus in Behrens apparatus drill guide block 90 is fixed threadably with socket 236 in intramedullary nail in parallel arrangement with distal locking screw direction in fixed position, further providing multiple sockets -

holes in intramedullary nail and making corresponding drill holes at multiple place in shaft of femur locating socket weakens the nail assembly by creating multiple stress risers in metal of nail wall and bone wall .

Present invention overcomes the above mentioned drawbacks found in the Zirkle or Behrens apparatus ,and in like apparatus common in prior art by providing structure and construction of a first plurality of proximal holes and first plurality of distal holes in intramedullary nail along with corresponding second plurality of proximal holes and second plurality of distal holes in targeting device such that plane of center of a first plurality of proximal holes in intramedullary nail is extending to midsection of head and neck portion of femur bone and is intersecting (not parallel) with plane of center of first plurality of distal holes of intramedullary nail extending through midsection of shaft of femur such that a plurality of proximal hip pins is engagable in midsection of head and neck portion through a first plurality of proximal holes slidably and simultaneously a plurality of locking screw is engagable in midsection of shaft of femur through a first plurality of distal holes without rotating a targeting device with intramedullary nail connected therewith. (Present applicationPara[[0005],[0016],[00028],[00040],[00086],[00087],[00096], Figs. , 9, 28 and 31 shown below.).



The structural combination of elements set forth in the present **claim1**, as well as the manner, in which that structural combination of elements is used, is distinctly different from that disclosed in Zirkle and subject matter of claim 1 of present invention is neither anticipated nor rendered obvious by the reference. Applicant further points out respectfully as disclosure in Behrens has been fully discussed above and proposed

combinations of Behrens with Zirkle is untenable in rendering obvious the subject matter of the present claim 1 and rejection requested be withdrawn.

On page 8 of the Final Office Action Examiner states that **Claims 27,2-3,7-8, 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 and Behrens US 6,932,818 as applied to claim 1 and further in view of Bosacco US 3,670,724. As mentioned above Independent Claim1 is amended to further describe applicant's invention and Applicant respectfully requests entry of amended independent Claim 1. Claims 27, 2-3,7-8 , 14-15 are also currently amended and dependent on amended Claim 1, Applicant respectfully requests entry of amended dependent Claims 27, 2-3,7-8 , 14-15.

On page 8 of Final Office Action regarding **claim2**, examiner has stated reference of Zirkle , paragraph [0035] where mention is of nail length of 12-24" and having shaft part capable of matching anterior curvature of bone ,where even though deflection of nail can occur leading to difficulty in locating distal holes in nail which is full length from 12-24", it seems that Zirkle describes this for concern of difficulty of locating distal holes in nail (emphasis added), while applicant describes in present claim 2 of having curvature in knee portion of intramedullary nail that is terminal portion in intramedullary nail of short length version capable to match anterior curvature of shaft of femur bone (Fig 7 of present application) to avoid abutting of nail tip at anterior cortex of shaft of femur as short length version nails having straight knee end described in similar prior art (Fig 6 of present application) has created problem of *stress concentration* by tip of knee end of nail leading to later on pain to patient requiring early removal of nail before complete healing and also fracture of concentrated stress at shaft just beneath the tip of knee end of nail. Zirkle or Behrens or Bossaco apparatus does not teach or suggest need for such structure in intramedullary nail.

On page 8 of Final Office Action regarding **claim3**, examiner has stated reference of Zirkle , paragraph [0032] and Fig.2, 3-3a shown to have connecting end jig short and compact and connecting only to top portion of nail and removable so as to not obstruct imaging, applicant respectfully argue that Zirkle apparatus if used (modified as Behrens having proximal holes directed towards head and neck of femur) for locating the first plurality of proximal holes in nail extendable to midsection of head and neck portion of

femur, it requires precise placement in centre of head and neck and to check its placement intraoperative imaging is required without removing connecting end of jig connected to top of intramedullary nail and real time imaging is required in front plane as well as side to side plane to precisely decide position of anchoring pin or screws in head and neck portion, here a T handle connecting intramedullary nail and parallel proximal targeting arm will obstruct –superimpose its image and obstruct the view of head and neck in side to side plane and it can't be removed while targeting.

On page 9 and 10 of Final Office Action regarding **claim 7 and claim 14**, examiner has stated reference of Zirkle, paragraph [0035] and Fig.2, shown to have “any number of distances in X or X1 can be made between the connecting end and the holes and proximal holes are at a distance Y or Y1, where distance between any given point can be always measured in millimeters.....”. Applicant respectfully argues that Zirkle or Behrens or Bosacco has not specifically mentioned about distance between connecting end of intramedullary nail and a first plurality of proximal holes in nail (X) or distance between connecting end of targeting device and a second plurality of proximal holes in targeting device (X1) and also not specifically taught or suggested about a distance in between a pair of a first plurality of proximal holes in intramedullary nail (Y) or in between pair of second plurality of holes in targeting device (Y1). Applicant found while using apparatus like Zirkle or modified like Behrens or other similar that (Present Application para [00018]) provide a plurality of holes directed towards a head and neck portion of femur bone and plurality of holes directed towards shaft of femur bone, apparatus does not have a specific distances as mentioned above as X and X1 , Y and Y1 capable to target a first hip pin near a calcar portion located inferiorly in neck portion of femur bone and which is very dense bone for better fixation and simultaneously capable to have placement of one another hip pin substantially avoiding superior surface of neck located superiorly in neck portion which is very weak to hold or engage hip pin , so surgeon has to accept placement of hip pin near superior surface leading to cut through and failure of fixation. Applicant found during research specific distances X, X1, Y, Y1 which avoids such complication in majority of proximal femur fracture fixation.

On page 9 and 10 of Final Office Action regarding **claim 8 and claim 15**, examiner has stated reference of Zirkle , paragraph [0035] and Fig.2, shown that “ nail can be of short length version where there is a distance Z or Z1 in millimeters between connecting end of

nail or targeting device.....” . Applicant respectfully argues that Zirkle or Behrens or Bosacco has not specifically taught or suggested about distance between connecting end of short length version of intramedullary nail and a first plurality of distal holes in nail (Z) or distance between connecting end of targeting device and a second plurality of distal holes in targeting device (Z1). Zirkle describes difficulty of locating distal holes due to deflection of nail in curved canal of bone even with the help of jig and also describes its solution by providing apparatus slot finder (Para [0037]) after drilling large diameter hole in near cortex to feel (in absence of real time imaging equipment) the aperture in nail and also further describes in certain situation where there is still difficulty in locating the distal hole by slot finder, he suggests [Para 0038] to even remove Jig 17 to have more freedom to surgeon to search the aperture 40 by rotating the slot finder. This may be due to long cantilever lever arm of distal targeting arm from connection of jig to IM nail, too many joining parts e.g. T handle with Nail, T handle with proximal targeting arm and proximal targeting arm with distal targeting arm and no other support to long targeting arm except connection at T handle and also due to difference in curvature of nail and bone and deflection of nail within medulla of bone. Due to long, cantilver arrangement of targeting arm , it allows lateral movement of distal targeting arm away from desired parallel alignment with nail , causing misalignment of the distal holes with corresponding holes in IM nail requiring larger diameter drilling in near cortex leading to larger incision and invasiveness. Applicant’s present invention provides specific distances Z and Z1 respectively for distal holes in nail and distal holes in targeting device at a distance of short lever arm and before anterior curvature of medullary canal of shaft of femur bone starts to avoid drawback of misalignment occurring due to deflection of nail within medullary canal of bone.

On page 10 of Final Office Action regarding **claim 27**, examiner has stated reference of Zirkle and Behrens in view of Bosacco. Claim 27 has been amended to further describe Applicant’s invention and support for such amendment is found throughout the specification, at, e.g. paragraphs [0024], [00036], [00048], [00086], [00087], [00089], [00092], [00093], [00096], and Figs. 3, 9, 15, 21, 24, 25, 28, 30 and 31. Amended dependent claim depends on independent claim 1 and applicant respectfully requests entry of amended claim 27. Applicant submits that “Bosacco” (US 3,670,724) teaches away from applicants amended claim 27 and does not render obvious amended claim 27 over Zirkle and

Behrens. For example Bosacco or Zirkle or Behrens do not teach or suggest plane of center of first plurality of proximal holes located in head part of intramedullary nail extending to midsection of head and neck portion of femur bone and plane of center of first plurality of distal holes located in shaft part of intramedullary nail extending to midsection of shaft of femur bone and both are intersecting with each other. Instead, as Bosacco teaches "intramedullary nail 17 as illustrated in Fig 9 is employed having a plurality spaced apertures 17a throughout most of its length " (Col. 2 ll 57-60) . Bosacco does not disclose plane of apertures 17 a extending through midsection of head and neck portion of femur or it discloses orientation of aperture 17a of intramedullary nail 17 as shown in Fig 7. - Bosacco (US 3,670,724.) of allowing engagement of sliding smooth part of proximal hip pins slidably in aperture 17a or aperture 22a of plate 22 and triflanged part engagable to head and neck portion of femur bone 19 (Emphasis added). Applicant also points out that because intramedullary nail 17 disclosed by Bosacco is not connectable with targeting device and method of its insertion is disclosed that "The nail 17 is driven in retrograde fashion through the medulla 19c of bone 19 and the fracture is reduced "(Col. 2 ll 61-63), because of this Bosacco teaches away from having insertion of intramedullary nail by invasive way by opening the fracture site. Bosacco does not disclose element of a plurality of barrels along with intramedullary nail and buttress plate which is essential in situations when lateral cortex of femur bone is broken very badly and there is fracture gap even after fixation and drilled hole in lateral cortex is not uniform due to broken lateral cortex there is no smooth uniform sliding surface for sliding of smooth sliding part of proximal hip pins and there is no lateral support or platform for controlled sliding of proximal hip pins to allow controlled collapse of fracture gap for bone to bone contact , where barrels along with buttress plate are essential to provide support and platform to broken lateral cortex and barrels provide uniform gliding surface . Applicant further points that Bosacco disclose a rigid member –intramedullary nail (Emphasis added) having a first set of spaced apertures and a rigid plate having a second set of apertures spaced from one another identically to the spacing of apertures in said first set (Col. 4 Claim 1 a. and b. ll.1-8), while applicants discloses first plurality of proximal holes of intramedullary nail and central large holes of buttress plate ; first plurality of distal holes of intramedullary nail and small holes in buttress plate are not identically placed though they match with each other in angular fashion and they are not

placed throughout most of length of intramedullary nail or plate. Applicant further points that Bossaco discloses requirement of making burr hole 19b drilled in lateral femoral shaft large enough so that at least one of the holes 17a would be visible through hole 19b (Col 2 ll 66-72), thus Bosacco teaches to make hole 19b in femur bone large enough to see by naked eye (emphasis added) hole 17a to provide fixed reference point which may not be exactly positioned for reference as not made with any reference targeting device and making such large hole will weaken further lateral cortex of femur bone and which is already weakened by fracture, which is contrary to teaching by applicant's disclosure. Bosacco teaches away by disclosing intramedullary nail 17 having plurality of spaced apertures 17a throughout most of its length (Col 2 ll; 57-60), this feature creates stress risers at multiple points and weakening the intramedullary nail and assembly which is likely not to withstand higher forces at proximal femur fractures. Applicant further points that Bossaco recites the method of treating human bone which requires exposure of bone on either side of fracture area and also fracture area to position rigid bone plate and to align identical second set of apertures in plate and first set of apertures in intramedullary rigid member and drill large enough hole in bone to make visible one of the first set apertures of rigid member placed in medulla of bone, further recites that plate is removed before fasteners are inserted (Col 4 ll 23-45), thus it appears that Bosacco intends to use plate member temporarily as internal guide only. Applicant further points that Bossaco discloses use of intramedullary nail placed inside medulla of bone and plate placed on exterior of bone, when finally fixed with fasteners through each other, it does not allow collapse of fracture gap and bone to bone contact later on weight bearing by patient, thus Bosacco teaches static fixation, which is contrarily to teaching by Applicant's disclosure. Applicant further points out that Bosacco teaches use of plate fixed on exterior surface of bone rigidly not to allow any movement between screw and nail and plate and also due to rigidity and compression hampers blood supply to external layer of bone that is periosteum which is very vital for new bone formation and healing of fracture, thus teaches away from applicants disclosure where plate is cooperating with intramedullary nail in buttress mode without hampering blood supply to the periosteum and allows backward movement of proximal hip pin within nail holes and barrels and central large holes of plate allowing collapse of fracture gap. Accordingly, Bosacco does not anticipate or render obvious dependent claim 27.

Applicant respectfully requests entry and allowance of Claim 27.

On page 12 of Final Office Action regarding **claim 18**, examiner has stated that claim 18 is unpatentable over references of Zirkle, Behrens, and Bosacco further in view of. Engelhardt et al US 4,805,607 Claim 18 has been amended to further describe Applicant's invention and support for such amendment is found throughout the specification, at, e.g. paragraphs ([00089], [00092], [00093], [00096], and Figs. 15, 17, 18, 19, 28, 30 and 31). Engelhardt et al US 4,805,607 discloses a modular two piece intramedullary nail 20 comprised of two major components, namely an elongated base nail 22 (Col. 3 ll 50 – Col. 4 ll 1-35, Figs. 2-3) and an extension member 24 intended for elective attachment to one end of base nail. The modular intramedullary nail 20 comprising base member is intended for the repair of long bone fractures, most notably femur and tibia and further described that, the base nail 22 is intended for placement in medullary canal of long bone like femur and preferably curved to a radius of approximately 60 to 80 inches. Engelhardt et al further teaches that mid region of base nail 22 has very deeply fluted or tri-flanged cross section shape and an extreme tip 28 of base nail at its leading end is moderately blunt, displaying a radius, for example, of approximately 0.125 inches, at trailing end of base nail 22, the flanges 26 are faired into cylindrical bearing region 32 and a pair of generally parallel, spaced apart, engagement tongs 34 extending away from bearing region 32 and are resilient in directions toward and away from each other for locking with extension member. Applicant respectfully argue that the structure of nail having base member 22 here is intended to be placed into hollow medullary cavity as opposite to applicant's intention to use such hip pin in cancellous dense packed bone of head and neck of femur bone which is not modular or has no curvature and it has sliding surface and fixed slidably through the a first plurality of holes of intramedullary nail, a plurality of barrels and central large holes of buttress plate and it has at its trailing end no element of structure for locking with any extension member and at leading it has triflanged surface and not at mid region. Applicant further argues that base nail 22 as taught by Engelhardt et al having deeply fluted or triflanged cross section will lead to more loss of metal from nail and weakening and increase the possibilities of breakage as nail placed in medullary canal of long bone like femur is subjected to more forces than compact dense bone of head and neck portion of femur bone. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the

according to amended claim 18, present invention is constructed structurally different from devices of Zirkle, Behrens, Bosacco in view of Engelhardt et al and is used in an entirely different manner, thereby overcoming drawbacks in cited references, as well as many similar devices known in the prior art of record. As such, cited references do not anticipate or render obvious dependent claim 18. Applicant respectfully requests entry and allowance of Claim 18.

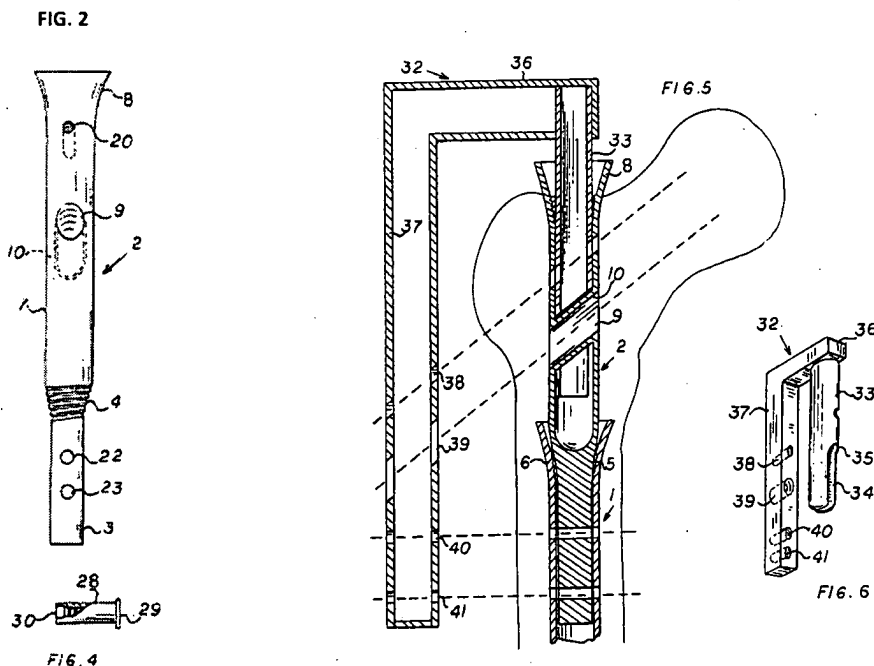
On page 14 of Final Office Action regarding **claim 21 and 24**, examiner has stated that claim 21, 24 is unpatentable over references of Zirkle, Behrens, Bosacco, Engelhardt et al and further in view of. Middleton et al US 2003/0083662. Middleton claims a in situ formed anchor where it is essential to form a pilot hole in the bone having first diameter and forming a cavity in bone connected with pilot hole and distal to pilot hole having second diameter which is substantially larger than first diameter and also requires to have performed implant element having holes as interlocking elements wherein there is substantial space between interlocking elements and boundary of said cavity, injecting a hardenable material into cavity to make insitu formed anchor to hold bone. Applicant points out that in situ anchor provided by Middleton is not the same as fixation assembly as described and claimed by applicant in amended claim 24. For example, with Applicant's claimed invention, proximal hip pin comprising triflanged part with multiple holes is specifically in direct contact with cancellous bone and not within any bone cavity that means there is no any substantial space between the triflanged part with multiple holes and bony tissue of head and neck of femur. This is not taught by Middleton. Middleton does teach to form a cavity surgically with the help of cavitations devices before placing anchoring implant in bone and teaches to have substantial space between placed implant and boundary of cavity where placed anchoring implant is not in direct contact with bony tissue, which is contrarily to Applicant's teaching. Making a cavitations in bone having substantially large diameter than the shaft or body of screw and filling this large cavity with cement or any harden able material has drawbacks of further weakening the bone and necrosis due to exothermic reaction to large amounts of such artificial material and it does not allow to have more than one anchors in head and neck of femur which is many a times essential to have for rotational stability and better fixation in osteoporotic bone in elderly, Applicant further points out that having substantially large cavity and having space between performed element and cavity

boundary , in cases where cavity is filled only partially there will be no full bondage between performed anchoring element and bone leading to loss of fixation and there will not be any second chance to improve the fixation. Together with arguments and the reasons set forth above, Applicant herewith has shown that Middleton does not make obvious applicants invention. Applicant respectfully requests rejection of claim under USC 103 (a) be removed.

On page 15 of Final Office Action regarding Independent method **claim 29**, examiner has stated that claim 29 is rejected under USC 103 (a) as being unpatentable over Marino US 4,733,654 in view of Weigum US 5,462,547 and further stated that Marino discloses Method of treating fracture..... Claim 29 has been canceled and new claim 31 is made in place of claim 29 to further describe Applicant's invention. Support for new claim 31 (in place of canceled claim 29) may be found throughout the specification,ate.g.paragraphs[[0024],[00036],[00048],[00086],[00087],[00089],[00092],[00093],[00096], Figs. 3,9,15,21,24,25,28,30 and 31. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the according to new claim 31(in place of canceled claim 29) and other claims, present invention is constructed structurally different from device of Marino and device of Weigum and is used in an entirely different manner, thereby overcoming drawbacks in the kit of Marino and device and method of Weigum, as well as many similar devices known in the prior art of record.

Kit of combinations disclosed by Marino comprises a standard routine intramedullary nail 1like Kuntscher and having proximal conical head 6 with threads, a extension member 2 with conical threaded distal tip for attachment with proximal head 6 of nail 1, thus intramedullary nail disclosed by Marino is two piece nail with joint with thread attachment (Col. 2 ll 30-50, Figs 1, 2). This joint weakens the assembly by creating stress riser at junction and there are all chances of opening up of joint during rotation. Applicants discloses a unitary- one piece intramedullary nail to avoid this drawback. A first bore 9 surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19 . This type of arrangement where barrel angularly joined with side plate 19 placed through bore 9 with sleeve 10 in extension member 2 requires large opening-bore in extension member leading to further weakening of nail and to

accommodate larger diameter hole – diameter of extension member has to be substantially large which will require more reaming of bone tissue and loss of bone near fracture area, hampering healing of fracture (Emphasis added). The second but smaller and unsleeved bore 20 is drilled to accommodate smaller pin 21 through the upper end of extension 2 at the same angle and parallel to the first bore 9. The distal tip 3 of the extension 2 is also drilled orthogonally to form two additional bores 22,23 which is in line with symmetrical bores 24 and 25 in the proximal end of nail 1, threaded pins (screws) 26 and 27 engage said bores in order to stabilize the proximal end of nail 1. For further stabilization the side plate 19 is captured at its lower end through bores 31 by pins 26 and 27. Marino further discloses and recommends to install a grommet 28 into lined up bores 23 and 25 as well as bores 22 and 24 to immobilize extension member 20 within the nail in order to prevent rotation in between nail 1 and extension member 2, so it seems that Marino nail assembly has too many joints make the assembly weaker and joining these elements may hamper accuracy and precision. Marino further discloses and illustrates in Fig 5 and Fig 6 (as shown below) a drilling guide 23 adapted for use with extension member 2 comprising guide member 27 with plurality of bores 38 through 41 which are in line with bores 20,9 and bore 22,23 and 24,25 of extension member 2 and nail 1. The positioning leg 33 has bore 38 corresponding to bore 20 in the extension.



Applicant points out that plane of center of proximal holes 38 and 39 in drill guide 37 for proximal holes 20 and 09 respectively in extension 2, and plane of center of distal holes 40 and 41 in drill guide 37 for corresponding holes 22 and 23 in extension member 2 and corresponding holes 24 and 25 in nail 1 is parallel with each other (Fig 2,5and 6), and with this parallel arrangement of combination of structure of elements of proximal holes 20,9 ,38,39 and distal holes 40,41 , 22,23 ,24,25 don't allow engagement of proximal hip pins 11 and 21 in midsection of head and neck of femur bone and engagement of threaded pins 26 and 27 in midsection of shaft of femur bone simultaneously with anatomical reduction of fracture. Applicant points out that with applicant's invention, buttress plate 50 having narrow obtuse end 84 is slid on surface of greater trochanter 3 and lateral cortex 22 of femur from first small incision at tip of greater trochanter 3 and slit 86 helps in positioning of buttress plate at second small incision at lateral cortex 22 without much soft tissue dissection (Present application para [00093],[00096],Figs 24,25). Applicant further points out that for inserting angled barrel member with plate as disclosed by Marino and Weigum requires large incision by open method and tissue dissection of lateral cortex which is already broken very badly having less blood supply from soft tissue and will require large diameter drilling for angled barrel member 18 which will lead to further weakening of lateral cortex of femur bone which is already broken very badly and further hampering platform for controlled collapse of fracture gap, which teaches away from applicant's disclosure of minimal invasiveness . Applicant respectfully argues that Kit provided by Marino has composite fixation pin 11 to engage head and neck of femur through angled barrel member 18 of plate 19 in dynamic mode and another pin 21 out of plate 19 in static mode and if Marino plate 19 is modified in view of Weigum plate as stated by examiner then also fixation pin 11 is engagable in dynamic mode and another pin 21 through the hole in modified plate according to Weigum not having any barrel member is still in static mode even after modification according to Weigum , makes whole assembly practically in static mode. In such condition once final fixation is done and during rehabilitation of patient, when patient starts walking, even with partial weight bearing , forces will be uneven as there is no anatomical reduction with parallel arrangement of plane of proximal holes and distal holes as stated above in discussion of structure of Marino's kit

and further due to , even after modification of Marino plate according to Weigum pin 21 is fixed in static mode will not move backward on body forces and will not allow collapse of fracture gap or if force is larger fixation pin 11 or 21 or both will penetrate head of femur into hip joint which will cause pain and will fail the very purpose of fixation. As such, even with Marino plate 19 modified according to Weigum, resultant assembly does not provide fixation which allows controlled collapse of fracture - and does not provide application of plate by minimal dissection of soft tissue taking care of biology using minimal invasive technique. Present invention disclosed by applicant provides even distribution of forces due to structure and construction of planes of proximal holes and distal holes intersecting with each other, provides dynamic mechanical fixation, thus providing controlled collapse of fracture and provides fixation with taking care of biology in minimally invasive way. So applicant respectfully argues that applicant's invention as a whole structurally and functionally different from disclosed Marino's kit and even on application of technique of Weigum trochanter plate on Marino's kit does not yield predictable and improved results leading to improved resultant assembly and also modification of Marino's kit in view of trochanteric plate of Weigum or combining teachings of references does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at independent claim 31 of present invention. Applicant respectfully requests entry of claim 31 (new claim in place of cancelled claim 29).

On page 17 of Final Office Action regarding dependent claim 30, examiner has stated that claim 30 is rejected under USC 103 (a) as being unpatentable over Marino US 4,733,654 and Weigum US 5,462,547, and further in view of Vandewealle 5, 810,821. Applicant respectfully submits that claim 30 is cancelled and new claim 32 is added in place of cancelled claim 30. As claim 32 depends on claim 31, as discussed above, applicant requests entry and allowance of claim 32.

Conclusion

Consideration for and allowance of the pending claims in this Application, as provided in the Listing of Claims beginning on page three of this paper are respectfully requested for the reasons set forth herein. In light of amendments, remarks and arguments presented with this paper, Applicant respectfully submit that the pending and amended claims are in

condition for allowance. No new matter has been introduced with this Amendment.

This amendment is timely filed with request for extension of time under CFR 1.136 and Request for Continued Examination under CFR 1.114 and with appropriate fees for both. No additional fees are believed due with this response. If this is incorrect, the Commissioner is authorized to charge such fees, other than the issue fee, that may be required by this paper to Deposit Account No: 20-0674.

If the Examiner has any question or comments or if further clarification is required, it is requested that the Examiner contact the undersigned pro se inventor at the telephone number: +91 9825387016.

Date: March 30, 2009

Respectfully submitted,
/Navin N Thakkar/
Signature
Printed Name: Navin N Thakkar
Pro Se Inventor
Customer Number: 86798(recently allotted)